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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,289	05/29/2001	Peter A Lambert	PM-275343/C1	8932

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,289	LAMBERT ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 30 September 2002 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 and 7-36 is/are pending in the application.

4a) Of the above claim(s) 1-5,7 and 16-34 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-15,35 and 36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 May 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The request filed on 30 September 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/701,289 is acceptable and a CPA has been established. The 3-month suspension under Rule 103(b) for a period of three months has expired. An action on the CPA follows.

Specification

2. The specification is objected to because of the following informalities: page 3, paragraph 3, last line has typed written words that are illegible. A submission of a new page 3 is required.

Claims Objections

3. Claim 13 is objected to because of it recites the names of genus of microorganisms, for example *Stapholococcus* which should be italicized. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim 9 recites the term "obtained from". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "obtained from" cannot be ascertained. Clarification as to the meaning of this term is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8-13, 15 and 35-36 are rejected under 35 U.S. 102(b) as anticipated by Wergeland et al (*Journal of Clinical Microbiology, June 1989, p. 1286-1291).*

Claims 8-13, 15 and 35-36 are drawn to a method of testing for a gram-positive bacterial infection in a mammalian subject, the method comprising the steps of: obtaining a sample of body fluid from the subject, contacting the sample with a composition comprising a compound having the structure shown in Figure 2, wherein n is an integer between 3 and 10 (inclusive) and X is H, OH, alkyl, aryl, amyl or an amino acid residue, which may be substituted or a sugar reside, which may be substituted and R and R^1 may be the same or different and are hydrophophic or fatty acid chains and detecting binding of antibodies, if any in the sample to the composition.

Wergeland et al teach a method of analyzing sera obtained from 66 blood donors wherein the sample is contacted with a Staphylococcal antigen composition comprising Lipoteichoic acid, LTA (the compound of Figure 1), peptidoglycan, β-ribitol teichoic acid

and peptidoglycan epitopes L-lys-D-Ala-D-Ala, L-lys-D-Ala and pentaglycine using an enzyme-linked immunosorbent assay (ELISA) in which the composition was done by standard procedures with polystyrene enzyme immunoassay plates (page 1287, 1st column) (composition bound to solid support). Wergeland et al teach the antibodies react with staphylococcal antigens. Wergeland et al also teach the range of antibody values in the sera from the blood donors and patients with various staphylococcal infections are shown in Table 1 (page 1287). Wergeland et al teach that the total immunogloblin G (IgG), IgA and IgM were routinely determined by the immunological laboratory procedures for all blood donor and patient sera with a Nephelometer-Analyzer. Wergeland et al teach that the normal ranges of the immunoglobulin concentrations in adult sera were the ranges 7 to 18, 0.5 to 3.3 and 0.3 to 2.5 g/liter for IgG, IgA and IgM, respectively. Wergeland et al teach the use of a 5 μg/ml concentrated LTA in the ELISA assay. Wergeland et al teach that the LTA was purified from *S. aureus* (page 1286, 2nd column). Wergeland, et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 8-15 and 35-36 are rejected under 35 U.S. 102(b) as anticipated by Carruthers et al (*Journal of Clinical Microbiology, April 1984, p.552-554).*

Claims 8-15 and 35-36 are drawn to a method of testing for a gram-positive bacterial infection in a mammalian subject, the method comprising the steps of: obtaining a sample of body fluid from the subject, contacting the sample with a composition comprising a compound having the structure shown in Figure 2, wherein n is an integer between 3 and 10 (inclusive) and X is H, OH, alkyl, aryl, amyl or an amino acid residue, which may be substituted or a sugar reside, which may be substituted and R and R^1 may be the same or different and are hydrophophic or fatty acid chains and detecting binding of antibodies, if any in the sample to the composition.

Carruthers et al teach a method of detecting antibody to staphylococcal Lipoteichoic acid (LTA) in a microenzyme-linked immunosorbent assay. Carruthers et al teach detection of antibody to cell components and extracellular products of *Staphylococcus aureus* solely or in combination may be useful in the serological diagnosis of serious *S. aureus* infections. Carruthers et al teach a purified staphylococcal LTA in a microenzyme-linked immunosorbent assay to examine human sera for antibody to the antigen (page 552, 1st column). Carruthers et al teach that sodium carbonated buffer and LTA were incubated overnight in a 96-well polystyrene microtitration plate (composition bound to solid support) and the unbound LTA was removed by suction (page 552, 2nd column). Carruthers et al teach that sera used in the microenzyme-linked immunosorbent assay was obtained from patients with prosthetic joint infections, patients with soft tissue infections, patients that had intravenous

catheter-associated bacterial infections and one patient with an infected shunt (page 552, 2nd column). Carruthers, et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
July 3, 2003

PATRICIA A. DUFFY
PRIMARY EXAMINER